

Exhibit B

Michael Thomas Margolis, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

In Re: Ethicon, Inc. Pelvic Repair
System Products Liability Litigation
Master File No. 2:12-MD-02327
MDL No. 2327

This Document relates to:
CAROLYN LEWIS, et al.,

Plaintiffs,

-vs-

Case No. 2:12-CV-04301

ETHICON, INC.,

Defendants.

DEPOSITION OF MICHAEL THOMAS MARGOLIS, M.D.

DATE: November 25, 2013
TIME: 9:20 a.m.
LOCATION: Pulone Reporting Services, Inc.
1550 The Alameda
Suite 150
San Jose, California 95126
REPORTED BY: Diane S. Martin, CSR 6464, CCRR

Michael Thomas Margolis, M.D.

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<p>1 use for a medical device?</p> <p>2 A. Well, again, other than lecturing to the FDA</p> <p>3 and lecturing all over the country on the risks</p> <p>4 associated with slings in particular and meshes, I</p> <p>5 haven't written it down, but I have lectured all over</p> <p>6 on it.</p> <p>7 And, of course, I'm familiar with the IFUs as</p> <p>8 I use them every day in my practice as well as in my</p> <p>9 teaching, including teaching to residents and fellows</p> <p>10 and attendings physicians all over the country. So I</p> <p>11 use them. And I lecture on them regularly.</p> <p>12 Q. I'm sorry, objection. Move to strike. That</p> <p>13 wasn't my question.</p> <p>14 My question was, have you ever been involved</p> <p>15 in drafting an IFU?</p> <p>16 A. Well, I'm going to hold to my answer, because</p> <p>17 that's -- that's the answer.</p> <p>18 Q. I'm not asking -- I know you were involved</p> <p>19 with the FDA. You were there. You talked to the ag</p> <p>20 com. I'm familiar with all of that. My question is</p> <p>21 very straightforward and simple.</p> <p>22 Have you ever been involved in drafting an</p> <p>23 IFU?</p> <p>24 A. The answer is other than lecturing on it and</p> <p>25 using it and using it as part of my teaching, no.</p>	<p>1 Q. What about the SIS product for Cook that you</p> <p>2 used, the porcine pig small bowel, when is the last</p> <p>3 time you looked at the IFU for that?</p> <p>4 A. Back recently. I mean, that's -- that's a</p> <p>5 recent study that we were working on. In fact, I</p> <p>6 was -- I mean I was, you know, intimately involved in</p> <p>7 the -- in working with the engineers on that product</p> <p>8 because I was the technical surgeon who was helping</p> <p>9 them work out their operative protocols on that device</p> <p>10 that we were trying to develop. We were building a new</p> <p>11 fistula plug.</p> <p>12 Q. That's not the SIS product for Cook; is it?</p> <p>13 A. Cook has an SIS product for rectovaginal</p> <p>14 fistulas. We were working on a novel fistula plug for</p> <p>15 vesicovaginal fistulas. We were working to transpose</p> <p>16 their RVF plug to a VVF plug.</p> <p>17 Q. The SIS product by Cook, which was the porcine</p> <p>18 pig small bowel, I thought that was a sling-type</p> <p>19 material you had used a few times?</p> <p>20 A. Okay. So good question. It's the same</p> <p>21 material. The sling -- the SIS material, the porcine</p> <p>22 bowel submucosa can be used in the form of a sheet for</p> <p>23 hernia and prolapse. It can also be made into a plug,</p> <p>24 which is used for fistulas. So they use the same</p> <p>25 material, but in different applications.</p>
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<p>1 Q. Move to strike everything before "no."</p> <p>2 When is the last time you looked at a Gortex</p> <p>3 IFU?</p> <p>4 A. I haven't used -- haven't looked at a Gortex</p> <p>5 IFU recently. I've been using it for long enough and</p> <p>6 it hasn't changed.</p> <p>7 Q. When is the last time you looked at an IFU for</p> <p>8 the Boston Scientific Xenform sling?</p> <p>9 A. Within the last year.</p> <p>10 Q. When is the last time you looked at the</p> <p>11 Coloplast human cadaveric fascia IFU?</p> <p>12 A. Probably within the last two years.</p> <p>13 Q. When is the last time you looked at the Boston</p> <p>14 Scientific Repliform IFU?</p> <p>15 A. Last time I used it. Several years ago.</p> <p>16 Q. Would you typically look at an IFU every time</p> <p>17 you do a procedure?</p> <p>18 A. Any new instrument or material that I use</p> <p>19 that's new to me or that I'm teaching about, I will</p> <p>20 utilize the IFU in my analysis and my expertise or my</p> <p>21 usage of it until, of course, I get to the point like</p> <p>22 with Gortex where nothing has changed with Gortex for a</p> <p>23 long time. So I don't use that. IFU since nothing has</p> <p>24 changed. But with newer devices and newer products</p> <p>25 that I start using and when I teach, I utilize the IFU.</p>	<p>1 Q. What Ethicon products besides Prolene have you</p> <p>2 used in your career?</p> <p>3 A. Ethicon? I used their trocars. I love their</p> <p>4 trocars. Some of their instruments are good</p> <p>5 instruments. Needle drivers and the like. But most of</p> <p>6 what I use from Ethicon is the trocars or the preferred</p> <p>7 trocars. I argue with the hospitals to use them.</p> <p>8 Q. Is that the laparoscopic trocars?</p> <p>9 A. The laparoscopic trocars, yeah. I argue. I</p> <p>10 try to get the hospitals to use them. They like to get</p> <p>11 the cheaper ones, but the Ethicon are better.</p> <p>12 Q. Besides the TVT and TVT-O IFUs, have you</p> <p>13 reviewed other manufacturers' IFUs --</p> <p>14 A. I have.</p> <p>15 Q. -- for polypropylene slings?</p> <p>16 A. I'm sorry. I shouldn't have interrupted you.</p> <p>17 Yes, I have.</p> <p>18 Q. Which ones?</p> <p>19 A. Every single one of the synthetic slings out</p> <p>20 there.</p> <p>21 Q. Have you ever been involved -- strike that.</p> <p>22 Have you ever participated in the drafting of</p> <p>23 a patient brochure?</p> <p>24 A. A patient brochure?</p> <p>25 Q. And I'm going to cast a broad net. I mean for</p>